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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,011	10/25/1999	MICHAEL SIMONS	BIS-043/CIP	1306

7590 05/30/2003
DAVID PRASHKER PC
P O BOX 5387
MAGNOLIA, MA 01930

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/30/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,011

Applicant(s)

SIMONS ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This office action is in response to Paper No: 26, received 4/24/03, in which applicant elected group III, claims 11-14 with traverse. Applicant made no election of patentably distinct species regarding SEQ ID NO, cell type, or tissue type.

Applicant traversed the restriction requirement stating that the restriction is procedurally inappropriate and unfair. Applicant points out that the claims have been of record since 10/99.

Applicant claims that the examiner has failed to provide any acceptable reasoning or rational basis for views that methods of claims 1 and 2 are unrelated to PR-39 oligopeptide defined by claim 11. Examiner directs applicant's attention to Paper No:25, page 4, first paragraph of the restriction requirement for reasoning regarding the restriction requirement.

Applicant's identification of SEQ ID NO: 3 as a representative embodiment of PR-39 in the response has been interpreted as an election of that sequence for prosecution on the merits (claim 12). Since applicant did not address examiner's request for an election of patentably distinct species regarding cell type, tissue type, and means of introduction, the species will be examined in the order listed in the claims. Claims 13 and 14 are withdrawn from consideration as directed to a non-elected invention.

Claims 11 and 12 will be examined to the extent that they read on the elected sequence, SEQ ID NO: 12

While applicant's arguments regarding the previous prosecution history are noted, the examiner is not bound by that history, as there were previously no available sequence listings for searching (Paper #9, 12/20/00).

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The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11 and 12 are provisionally rejected under the judicially created doctrine of double patenting over claims 11 and 12 of copending Application No. 09/276,868. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claim 11 of the instant application recites a family of PR-39 derived oligopeptides whose members individually cause an alteration in proteasome-mediated degradation of at least one identifiable peptide in-situ after introduction intracellularly to a viable

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cell, each member of said PR-39 derived oligopeptide family being less than 26 amino acids in length. Claim 11 of the '868 application recites the same. Claim 12 of the instant application recites a PR-39 derived oligopeptide comprises of 15 amino acid residues whose sequence is SEQ ID NO: 3. Claim 12 of the '868 application recites the same.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallo, USPN 5,654,273.

The instant invention is drawn to a family of PR-39 derived oligopeptides whose members individually cause an alteration in proteasome-mediated degradation of at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family being less than 26 amino acids in length. The PR-39 derived oligopeptide comprised of 15 amino acid residues whose sequence is SEQ ID NO: 3. The present invention envisions and permits a diverse range of means for introducing native PR-39 peptide or a shorter length peptide, see page 9, line 6. Both the shorter length PR-39 and native PR-39 demonstrated induction of angiogenesis, see page 46, lines 21-22. Regulation is performed using

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native PR-39 peptide or one of its shorter length homolog, for interaction with such proteasomes as one present in the cytoplasm of viable cells.

Gallo teaches PR-39 and derivatives as useful in the process of angiogenesis, see abstract. Gallo discloses PR-39 is a 39 amino acid sequence shown in sequence ID NO:1, column 3, lines 25-35 and column 11, SEQ ID NO: 1 which has 100% sequence identity to SEQ ID NO: 3 of the instant application, GenCore version 5.1.4, page 2, result # 4. While Gallo does not specifically teach that a 39 amino acid sequence of PR-39 causes an alteration in proteasome-mediated degradation of at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, absent evidence to the contrary, native PR-39 peptide disclosed by Gallo would inherently possess this property.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT

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5/22/03

RT

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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